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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,636	10/16/2001	James D. Marks	407T-897710US	7011

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QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.
P O BOX 458
ALAMEDA, CA 94501

EXAMINER
LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/981,636

Applicant(s)

MARKS ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-72 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-15, drawn to methods for the identification of ligands internalized into a cell, classified in class 435, subclass 7.2.
 - II. Claims 16-31, and 56-58, drawn to methods for the identification of receptors that internalize ligands, classified in class 435, subclass 7.2.
 - III. Claims 32-43, 54, and 55, drawn to ligand libraries, classified in class 435, subclass 7.1. (For the purposes of this restriction, claims 36-38 are being read as though the term “method of claim 33” was a typographical error, and the Applicant intended these claims to further identify the library of claim 33. If this is an incorrect interpretation of the claims, and the Applicant wishes to elect either Group III, or a method intended by the language of claims 36-38, the Applicant is requested to clarify what is meant to be encompassed by these claims).
 - IV. Claims 44-53, drawn to constructs comprising a ligand, an effector, and an epitope tag, classified in class 430, subclass 350.
 - V. Claims 59-61, drawn to methods for the identification of ligand internalization modulators, classified in class 435, subclass 7.2.
 - VI. Claims 62-65, drawn to a metal chelating lipid, classified in class 536, subclass 1.11.

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- VII. Claims 66-68, drawn to methods for the delivery of an effector into a cell, classified in class 514, subclass 2.
- VIII. Claims 69-72, drawn to compositions comprising a lipid, and hydrophilic polymer, and a chelation group; a ligand comprising an epitope tag; and an effector associated with the lipid, classified in class 514, subclass 2.

For each of Groups I-V, VII, VIII above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-VIII, and, if one of Groups I-V, VII, or VIII is elected, then election is also required to one of inventions (A)-(D). The subinventions of Groups (A)-(D) comprise the elected invention wherein the ligand is:

- (A) a peptide ligand;
- (B) an antibody ligand;
- (C) a cytokine ligand; or
- (D) a growth factor ligand.

The inventions are distinct, each from the other because of the following reasons:

- 2. The inventions of subgroups A-D are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions relate to inventions comprising, or relating to ligands of different structures, have different modes of operation, and perform different functions. Because each of the ligands performs a different function, has a different structure, and a different mode of operation (binds to a different receptor) the inventions relating to these different types of ligands are distinct
- 3. The inventions of Groups I, II, V, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions each relate to methods that perform a different function, or have a different mode of operation of a different effect. The different methods are therefore distinct.

4. The inventions of Groups III, IV, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions each relate to different compounds or compositions. Because these compositions have different structures, and are disclosed as performing different functions, they are distinct one from another.

5. The inventions of Group VIII are related to Groups IV and VI as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination includes limitations that may be relied on for patentability that are not present in the subcombinations. The subcombination has separate utility such as use in the method of Group VII.

6. The inventions of Group III and Groups I and II are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of

using that product (MPEP § 806.05(h)). In the instant case, because the composition of Group III may be used in any of the different processes of Groups I, II, or for the identification of modulators of ligand internalization (e.g. antibodies, agonists, and antagonists of the ligands), the ligands are distinct from the methods of Groups I and II as useful in the practice of materially different processes.

7. The inventions of Group IV and Groups I, II, and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the claimed product may be used in any of the methods of Groups I, II, or VII. Thus, the claimed construct may be used for different purposes, and is therefore distinct from any one of the indicated processes.

8. The inventions of Group VI and Group VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the metal chelating lipid may be used in the method of Group VII, or may be used in methods of depleting a composition of metal ions, or may be used in the making of liposomes, which in turn may be used in the processes of Groups I or II. The lipids are therefore distinct from the methods of Group VII.

9. The inventions of Group VIII and of Groups I, II, and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can

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be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products indicated in Group VIII may be used in any of the methods of Groups I, II, or VII. The composition is therefore distinct from each of those Groups.

Species Election

10. This application contains claims directed to the following patentably distinct species of the claimed invention: In each of Groups I-IV, the claims further identify species of inventions comprising different epitope tags, and different reporter/effector moieties. If the Applicant elects any of Groups I-IV, Applicant is further required to elect one each of

- a. An epitope tag from (e.g.) claim 9; and
- b. A reporter/effector moiety from (e.g.) claim 10.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 16, 32, and 44 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

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limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

11. Because these inventions are distinct for the reasons given above, have acquired a separate status in art because of recognized divergent subject matter and different classifications, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

12. It is here noted that some of the restrictions requirements made above fall within the scope of PTO Linking claim practice. In accordance with this practice as described in MPEP 809.03, linking claims will be considered with the elected invention. If the elected invention is found allowable, the linking claim will also be examined. If no substantive rejection is found for the linking claim, the restriction among the Groups it comprises will be withdrawn. Claims 1, 16, 44, 59, 66, and 69 are considered linking claims.

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13. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

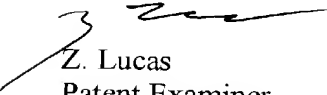
14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas
Patent Examiner



JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600